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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,073	02/24/2004	Michael T. Carley	16497.1.1.2.1	9513
57360 7590 11/12/2008 WORKMAN NYDEGGER 1000 EAGLE GATE TOWER, 60 EAST SOUTH TEMPLE SALT LAKE CITY, UT 84111				
EXAMINER TYSON, MELANIE RUANO				
ART UNIT		PAPER NUMBER		
3773				
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11/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/787,073

Applicant(s)

CARLEY ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008 and 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 8/21/08 & 10/22/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 21 August 2008 and 22 October 2008 have been entered.

Response to Arguments

Applicant's arguments, see lines 7-18 of page 8, filed 21 August 2008, with respect to the Spence and Gifford references and amended claims 1 and 17 have been fully considered and are persuasive. The rejection of claims 1-23 has been withdrawn and a new rejection is set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 7, 10, 11, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by **Loshakove et al. (U.S. Publication No. 2005/0283188 A1)**.
Loshakove discloses a device for engaging tissue comprising a generally annular

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shaped body (1100) having a plurality of looped elements (1102) comprising alternating first (inside) and second (outside) curved regions (for example, see Figure 16B) forming a zigzag, or sinusoidal, pattern about the central axis, wherein the first and second curved regions define inner and outer peripheries of the body. The body is expandable between expanded and compressed states (for example, see paragraphs 13 and 24) and may be superelastic (for example, see paragraphs 13 and 69), thus the body is movable as claimed. Loshakove also discloses at least one first primary tine (for example, two adjacent 1104's on the left side) extending from a first curved region of a looped element offset from the axis of symmetry of the looped elements (for example, see Figure 16B; one to the right and left of the axis of symmetry of the looped element) and at least one second primary tine (for example, two adjacent 1104's on the right side positioned on a looped element directly opposite the looped element on which the first primary tines are positioned) extending from a first curved region of a looped element offset from the axis of symmetry of the looped elements (for example, see Figure 16B; one to the right and left of the axis of symmetry of the looped element) towards the at least one first primary tine, wherein the primary tines may be bent (for example, see paragraph 133) thus are considered deflectable as claimed. Figure 16B further shows the body is biased towards the planar configuration, or compressed state, for biasing the primary tines generally towards the central axis. Loshakove further discloses the tines and body may be formed from a single sheet of sheet of material (for example, see paragraph 69).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 12-14, and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Loshakove et al.**

Regarding claim 5, Loshakove fails to disclose the superelastic material comprises a superelastic alloy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the superelastic body and tines from a superelastic alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Regarding claims 12-14, 18, and 19, Loshakove fails to disclose the primary tines are connected to the first curved regions of the looped elements by or curved or straight connector element. It would have been obvious to one having ordinary skill in the art at

the time the invention was made to connect the primary tines to the curved regions by a straight or curved connector element, as opposed to a direct connection, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Regarding claims 20-23, Loshakove fails to disclose the primary tines overlap the first curved region which is opposite the first curved region from which the primary tine extends. It would have been an obvious matter of design choice to form the primary tines such that they overlap the curved regions as claimed, since such a modification would have involved a mere change in size of the primary tines (i.e., lengthening the primary tines). A change in size is generally recognized as being within the level of ordinary skill in the art.

Claims 3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Loshakove et al. in view of Spence et al. (U.S. Patent No. 6,488,692 B1**; cited on 892 dated 9/5/07). Loshakove further discloses a set of secondary tines (the remainder of 1104; for example, the top four make two pairs of adjacent tines and the bottom two make one pair of adjacent tines), each pair of adjacent tines having a first (inside) curved region disposed therebetween (for example, see Figure 16B). The secondary tines may be bent (for example, see paragraph 133) thus are considered deflectable as claimed. Loshakove fails to disclose the secondary tines having shorter lengths than the primary tines.

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Spence discloses a device for engaging tissue comprising a generally annular shaped body having a plurality of looped elements and tines (for example, see Figures 9A-9F). Spence teaches a set of secondary tines (56) positioned on either sides of the primary tines (66), wherein the secondary tines have a shorter length than the primary tines. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Loshakove's secondary tines having shorter lengths than the primary tines as taught by Spence. Doing so would reduce overall tissue penetration by the device, thus reducing the possibility of infection and/or scarring.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of **U.S. Patent No. 7,211,101 B2**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of patent claims anticipate the examined application claims and some of the examined application claims would have been obvious over the patent claims.

Since the patent claims recite at least one primary tine being deflectable and offset, the patent claims anticipate some of the examined application claims reciting a second primary tine being deflectable and offset. Furthermore, a plurality of alternating loops defining an endless zigzag pattern inherently comprises a sinusoidal pattern, and the first and second curved regions inherently define inner and outer peripheries.

To modify the lengths of the tines such that they overlap the curved regions when the body is moved towards transverse configuration, and connect the tines to the looped elements by a connector element having the shapes claimed would have been obvious variations. The applicant has not disclosed that such configurations provide advantages, are used for particular purposes, or solve stated problems and it appears the patent claimed invention configurations would perform equally well.

Accordingly, the examined application claims are not patentably distinct from the patent claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Caro et al. (U.S. Publication No. 2004/0092968 A1)** discloses a

clip for engaging tissue comprising a generally annular shaped body movable from a substantially planar configuration towards a transverse configuration, the body being biased to return toward the planar configuration from the transverse configuration (for example, see Figure 13 and paragraph 27). Caro fails to disclose tines as claimed. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify Caro as taught by the prior art, since Caro teaches away from barbs or teeth that penetrate tissue (for example, see paragraph 27).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
October 30, 2008